American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Statement

of the

American Medical Association

to the

Practicing Physicians Advisory Council

RE: Pay for Performance Initiatives
Recovery Audits
Part D Prescription Drug Program
Competitive Acquisition for Drugs

May 23, 2005

Division of Legislative Counsel
202 789-7426

AMA RECOMMENDATIONS FOR PPAC

The AMA urges the Practicing Physicians Advisory Council to recommend that CMS —

RECOVERY AUDITS

- **Continue its emphasis on using the RAC demo to educate providers and physicians and to promote accurate billing and payment;**

- **Provide appropriate, advance notification to the physician community should the RAC demo focus on Part B claims;**

- **Continue to encourage the RACs to focus on areas that clearly indicate billing misunderstandings or other problems, as opposed to areas where multiple interpretations of billing policy are likely;**

- **Continue to ensure that providers and physicians retain throughout the RAC demo all of their current appeals rights, as well as the protections established under current law and regulations, including the due process protections of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as CMS has assured;**

- **Ensure that the RACs exclude review of correct coding with respect to Evaluation and Management (E&M) codes, as CMS has indicated, and clarify the scope of an E&M correct coding exclusion;**

- **Ensure that CMS staff and RAC representatives visit each affected state for outreach and education;**

- **Ensure that the RACs clarify with providers or physicians where the RAC should send correspondence when requesting claims review information**. .

- **Ensure that the RACs send correspondence to the appropriate address, and that the RACs significantly educate physicians and other providers as to the identity of the RACs and how to fulfill their requests;**

- **Monitor incentives for the RACs to identify underpayments and ensure that underpayments are referred to the appropriate contractor for payment;**

- **Clarify that the RACs' scope of review activities on Part A claims will be limited to the Part A provider;**

PART D PRESCRIPTION DRUG PROGRAM

- **Ensure that a broad-based education program concerning enrollment in the Part D drug benefit is in place for Medicare beneficiaries;**

- **Ensure that the impact of the drug benefit is adequately reflected in the SGR;**

- **Require Medicare Advantage plans to provide beneficiaries with clear and standardized information on what is and is not covered by the plan, as well as on their cost-sharing obligations;**

COMPETITIVE ACQUISITION FOR DRUGS

- **Include a plan for protecting beneficiaries who cannot reimburse the vendor for the patient copays associated with drugs under the CAP program;**

- **Take an active role in averting projected cuts of 26% in the physician conversion factor over the next six years, including removal of physician-administered drugs from the SGR, retroactive to the SGR base year;**

- **Make the CAP available to all physicians for all drugs that are furnished incident to a physician's service beginning in 2006. If, however, CMS decides to phase in the CAP, then at the very least, CMS should include all of the "problem" drugs – e.g., the Part B drugs that physicians have reported are unavailable at ASP;**

- **If the agency chooses to phase in CAP one category of drugs at a time, the opportunity to acquire drugs through the CAP should be available to any specialty that requires the drug for any purpose, including off-label use;**

- **Fully implement the CAP nationwide, e.g., in all acquisition areas, from the start of the program;**

- **Ensure the process for ordering drugs be as user-friendly as possible, and structured to be as similar as possible to the way a physician currently orders drugs. The process for ordering drugs should include phone, fax, and the internet. CMS should specify in the final rule that these formats may be used;**

- **Make explicit in the final rule the vendor's obligation to fill every valid (e.g., properly complete) order received from a physician;**

- **Require that information about "anticipated date of administration" be changed to allow a range of dates on which administration is anticipated for a particular patient. It is not always possible to predict the exact date on which drugs will be administered;**

- **Allow physicians at least 30 business days after the date of drug administration to submit claims;**

- **Lay out more detailed criteria on what the agency would regard as an emergency to prevent misunderstanding and possible audits and repayment demands in the future;**

  CMS should consider the creation of a group of physicians and patients to help flesh out the definition of an emergency. In the meantime, emergency orders should be filled on a same-day basis when possible. If that is not possible, physicians should be allowed to buy the needed drug from a source other than the CAP vendor or take it from existing stock. They should then have two options: (1) order the drug from the vendor to replace their private stock or (2) bill for the replacement drug using the ASP methodology.

- **Address in the final rule the following questions relating to the disposition of unused drugs when there is no resolution between the physician and vendor about how to handle such drugs: If the vendor requires the physician to return the unused drug, is the physician required to comply? If the physician sends the drug back, is the physician allowed to charge the vendor for shipping fees? Could the vendor require the physician to mitigate the vendor's loss by offering to administer the drug to another Medicare patient?;**

- **Include in the final rule a provision allowing physicians to choose categories of drugs they wish to obtain from vendors;**

- **Simplify claims processing under the proposal as much as possible to alleviate the administrative burden on physicians, and to develop a mechanism to reimburse physicians for any additional administrative costs they incur for participating in the CAP; such payments should not be included in the SGR, or, if they are, should be adjusted for in the law and regulation component of the formula;**

- **Clarify the extent of the physician's responsibility to appeal denied claims. The physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations); further appeals should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.**

- **With regard to ensuring that vendors meet quality and product integrity standards: (i) prohibit vendors from opening drug containers; (ii) permit physicians to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised; (iii) require vendors to carry substantial liability insurance; (iv) require vendors to indemnify physicians for any losses they cause; and (v) audit vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth;**

- **Clarify the extent to which vendors may market to patients;**

- **Allow physician to obtain new drugs outside the CAP if it is impossible for vendors to do so, and prohibit vendors from making deletions or substitutions in the formulary mid-year;**

- **Allow physicians to change vendors or leave the program if there is a service problem with a vendor; and**

- **Lay out a process for dealing with situations where patients face substantial payment difficulties due to possible differences between the drugs covered under a supplemental policy (or lack thereof) and those provided by the vendor, monitor the situation closely.**

The American Medical Association (AMA) appreciates the opportunity to submit this statement to the Practicing Physicians Advisory Council (PPAC or the Council) concerning: (i) pay for performance initiatives, (ii) recovery audits, (iii) the Part D prescription drug program and (iv) competitive acquisition for drugs (CAP).

The AMA would like to welcome two new Members to PPAC — Gregory Przybylski, MD and Leroy Sprang, MD. We also congratulate Joe W. Johnson, DC, on his renewed term on PPAC. We appreciate your time and interest in advocating for the patient and physician community on critical health care matters facing our nation, and we look forward to working with each of you and the other Members of the Council in these important efforts.

In addition, we would like to advise PPAC that the Medicare Trustees recently predicted that Medicare payments to physicians will be cut by about 26% over six consecutive years, beginning January 1, 2006. The AMA has conducted a survey from February and March 2005 concerning physician responses to a 5% Medicare physician pay cut on January 1, 2006, and cumulative reductions of 31% from 2006 through 2013 (as forecast in the 2004 Medicare Trustees report.) Results from the survey indicate that if projected cuts in Medicare physician payment rates begin as scheduled in 2006:

- More than a third of physicians (38%) plan to decrease the number of new Medicare patients they accept;

- More than half of physicians (54%) plan to defer the purchase of information technology;

- A majority of physicians (53%) will be less likely to participate in a Medicare Advantage plan;

- About a quarter of physicians plan to close satellite offices (24%) and/or discontinue rural outreach services (29%) if payments are cut in 2006. If the pay cuts continue through 2013, close to half of physicians plan to close satellite offices (42%) and/or discontinue rural outreach (44%); and

- One-third of physicians (34%) plan to discontinue nursing home visits if payments are cut in 2006. By the time the cuts end, half (50%) of physicians will have discontinued nursing home visits.

The AMA is continuing to work with CMS and Congress to avert these cuts and ensure that a stable, reliable Medicare physician payment system is place for beneficiaries.

PAY-FOR-PERFORMANCE INITIATIVES

AMA Commitment to the Development of Effective Quality Improvement Programs

As the AMA has previously advised PPAC, we are committed to quality improvement. To this end, the AMA has undertaken a number of initiatives to achieve this goal.

Over the last five years, the AMA has spent over $5 million in convening the Physician Consortium for Performance Improvement for the development of performance measurements and related quality activities. Much of the Consortium's focus has been on achieving improvement in physician care for certain care-intensive conditions and preventive services. To date, the Consortium and its partners have developed almost 100 performance measures for 15 clinical areas: (i) adult diabetes; (ii) asthma; (iii) chronic obstructive pulmonary disease; (iv) community-acquired bacterial pneumonia; (v) coronary artery disease; (vi) heart failure; (vii) hypertension; (viii) major depressive disorder; (ix) osteoarthritis of the knee; (x) prenatal testing; (xi) colorectal cancer screening; (xii) influenza immunization, adult; (xiii) screening mammography; (xiv) problem drinking; and (xv) tobacco use cessation.

Further, the AMA has partnered with CMS in pilot testing AMA/Consortium measures in certain programs, including the (i) Doctors' Office Quality (DOQ) Project, (ii) DOQ-Information Technology (DOQ-IT) Project, (iii) Medicare Physician Group Practice Demonstration, (iv) Medicare Chronic Improvement Program (Sec. 721 of the MMA), and (v) Medicare Care Management Performance Demonstration Project (Sec. 649 of the MMA).

We are also continuing to develop CPT Category II codes intended to facilitate data collection about the quality of care rendered by physicians. These codes describe clinical components that may be typically included in evaluation and management services or other clinical services and, therefore, would not show up in administrative data. The codes are based on clinically valid, evidence-based performance measures. Category II codes are reviewed by the Performance Measures Advisory Group (PMAG), an advisory body to the CPT Editorial Panel. The PMAG is comprised of performance measurement experts representing the (i) AMA; (ii) Agency for Healthcare Research and Quality; (iii) CMS; (iv) Joint Commission on Accreditation of Healthcare Organizations; (v) National Committee for Quality Assurance, and (vi) Physician Consortium for Performance Improvement.

In addition to contributing to numerous National Quality Forum (NQF) quality measurement efforts as a NQF member, the AMA-convened Physician Consortium, CMS, and NCQA have jointly identified ambulatory measures of quality of care for chronic diseases. This measure set is currently under expedited review by NQF. The AMA is actively working to ensure timely NQF approval of this measure set, which is expected approximately July 2005.

The AMA has also participated in the efforts of the Ambulatory Quality Alliance (AQA). This multi-stakeholder initiative recently identified a subset, or "starter set" of the ambulatory measures under review by NQF. The AQA will focus on implementation issues in an effort to improve health care quality while at the same time reducing the burden on physicians faced with multiple and sometimes conflicting quality measurement sets from different public and private payers.

Finally, the AMA believes that pay-for-performance programs done properly have the potential to improve patient care, but if done improperly can harm patients, and, thus, as we have previously advised the Council, we developed the following principles in our ongoing effort to advance development and effective implementation of pay-for-performance programs. We appreciate that PPAC recommended, at its last meeting, that as CMS develops and implements pay-for-performance programs, these programs should remain in alignment with our principles:

- Ensure quality of care;
- Foster the relationship between patient and physician;
- Offer voluntary physician participation;
- Use accurate data and fair reporting; and
- Provide fair and equitable program incentives.

Critical Considerations In Developing Effective Pay-for-Performance Initiatives

The AMA is committed to working with CMS to develop effective quality improvement programs, including those that use financial incentives consistent with the above principles. To this end we suggest a number of critical factors for CMS to consider as it looks to develop pay-for-performance in Medicare.

Physicians will be hard pressed to undertake important quality initiatives that require costly infrastructure, such as IT, if they are facing steep payment cuts. With projected Medicare payment cuts of about 26% over six consecutive years, beginning January 1, 2006, many physician practices are heavily focused on simply keeping their doors open to patients. In addition, due to recent cuts, as well as the expectation of these additional cuts, many physicians have already been forced to delay investment in maintaining and improving office facilities, staff and equipment.

Additionally, although physician pay-for-performance programs have the potential to save money to the Medicare program as a whole, any resulting volume increases due to pay-for-performance on the Part B side of the program will contribute to additional cuts to physicians under the SGR system. Simply put, the SGR and pay-for-performance are not compatible and one system cannot work effectively along side the other.

Further, certain dynamics that are unique to the application of pay-for-performance programs to the myriad of physician practices and specialties must be considered and addressed, including such important issues as: (i) the ability to risk adjust data for fair comparison of physician performance, (ii) how to keep the data collection burden low

while at the same time maintaining accuracy of the data, (iii) level of scientific evidence needed in establishing appropriate measures, (iv) appropriate application of measures across different medical specialties and different sizes of physician practices, (v) how many patients are required for a valid sample size, (vi) ability to trace a performance measure back to one or many physicians involved in a patient's care, (vii) how to distribute payments when multiple physicians are involved in a patient's care, and without violating any fraud and abuse laws and regulations, and (viii) applying quality measures to physician practices, which typically operate as small businesses and are vastly different in their type and size across the country, in contrast to applying such measures to hospital systems that are significantly fewer in number and generally more homogenous in the types of services provided.

The AMA is committed to continuing our work with the federation and with CMS and the Congress in addressing these issues and developing a fair and ethical quality improvement system that enhances care for Medicare patients.

Finally, we understand that CMS plans to issue an advance notice of proposed rulemaking concerning pay-for-performance programs, and the AMA looks forward to the opportunity to provide CMS with our views on this important matter.

RECOVERY AUDITS

Section 306 of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) provides that the Secretary of the Department of Health and Human Services conduct a demonstration project "to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments" under Part A or B of the Medicare program. Payment to contractors may be made on a contingent basis and a percentage of amounts recovered shall be retained by the Secretary.

The recovery audit contractor demonstration (RAC demo) may not last longer than 3 years and must cover at least 2 states that are among states with (i) the highest per capita utilization rates of Medicare services and (ii) at least 3 contractors. The Secretary must submit a report on the demo to Congress no later than 6 months after completion of the demo, with information on the impact of the project on savings to Medicare and recommendations on the cost-effectiveness of extending or expanding the project. CMS has stated that it will contract with an independent evaluator to review and report the performance of the RAC demo, including a survey of physicians in the affected states.

The physician community is extremely concerned about the RAC demo and the AMA has met with CMS staff to ensure that our concerns are addressed. We greatly appreciate the strong commitment of CMS staff to work with the physician community, through the AMA and appropriate state organizations, to implement this demo as fairly as possible and to use it as an opportunity to educate providers and physicians about billing errors and not as a punitive device. **We further appreciate the responsiveness and diligence**

of CMS staff in addressing the following specific concerns of the physician community about the RAC demo, and we urge PPAC to recommend that CMS—

- **Continue its emphasis on using the RAC demo to educate providers and physicians and to promote accurate billing and payment.** CMS has stated that should the RACs eventually review any Part B claims, the agency will assess where the RACs are locating billing problem trends and work with the AMA, state societies, and others to educate physicians and providers in this area. CMS has also committed to working with the AMA and state medical societies on an education work plan. We agree with this approach and look forward to continuing to work with CMS in these efforts.

- **Provide appropriate, advance notification to the physician community should the RAC demo focus on Part B claims.** CMS has stated that the RACs will initially focus on Part A claims and will shortly provide the agency with a list of the types of providers whose claims they intend to review. CMS has also said it will share that information with the physician community. Further, if the RACs plan to examine Part B claims in the future, the RACs have committed to notifying CMS well in advance of any such intent. CMS would then advise the physician community of this expanded focus.

- **Continue to encourage the RACs to focus on areas that clearly indicate billing misunderstandings or other problems, as opposed to areas where multiple interpretations of billing policy are likely.** CMS has indicated that the RACs plan to focus on claims that have clear errors, as opposed to "gray" areas where disputes are more likely. This approach is supported by a couple of factors: (i) Medicare will pay the RACs based only on amounts they recover, and not simply for identified errors, and (ii) if a physician or provider successfully challenges a RAC's findings at the first level of appeal, the RAC will not be paid by Medicare. Again, the AMA agrees with this approach and we encourage CMS to monitor the RACs to ensure that this approach is adopted in practice.

- **Continue to ensure that providers and physicians retain throughout the RAC demo all of their current appeals rights, as well as the protections established under current law and regulations, including the due process protections of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as CMS has assured.**

- **Ensure that the RACs exclude review of correct coding with respect to Evaluation and Management (E&M) codes, as CMS has indicated, and clarify the scope of an E&M correct coding exclusion.**

  CMS has indicated that the RACs will not review whether E&M claims are correctly coded and that this exclusion will apply to: (i) code levels within E&M families (*i.e.*, office visits, hospital visits, and consultations), (ii) codes between E&M families, and (iii) the accuracy of modifiers as they are applied to CPT

codes. Any RAC review of E&M services should be limited to E&M services inappropriately provided within surgical global periods.

The AMA strongly cautions that allowing the RACs to review whether E&M services were medically necessary will be viewed by physicians as a deliberate reversal on the exclusion of correct coding review. It is very difficult to distinguish the correct use of E&M codes from the medical necessity for E&M codes. The guidelines in the CPT book on E&M use the nature of the presenting problem and the reason for the encounter as a proxy for medical necessity. E&M code level selection involves assessment of the nature of the presenting problem as a contributing factor. This assessment can moderate code selection because it is primarily based on the extent of history, medical decision making, and examination. For example, a physician may perform and document the required history, exam and medical decision making for a level 5 office visit, despite that the presenting problem was minor and not likely to permanently alter the patient's health status (thereby strongly suggesting the possibility of a lower E&M level.) Since E&M guidelines include the nature of presenting problem as an explicit contributory factor in E&M code selection, it is difficult to argue that review of medical necessity is not in fact review of correct coding.

- **Ensure that CMS staff and RAC representatives visit each affected state for outreach and education.** CMS and the RACs, as of the deadline for this written testimony, are scheduled to meet with the Medical Society of New York on May 19, and the agency and the RACs are currently working to finalize a meeting date with the California Medical Association and Florida Medical Association. The AMA appreciates this outreach.

- **Ensure that the RACs clarify with providers or physicians where the RAC should send correspondence when requesting claims review information**. In the past, physicians have encountered problems under the Comprehensive Error Rate Testing (CERT) in responding to requests from the carrier for information. For example, the carrier may send correspondence requesting information about a claim to a physician practice's billing address (since this is the same address where the carrier sends payments on claims). Yet, the appropriate address for such a request is the practice's medical records department, which may located in a completely different location than the billing department. In this case, the physician practice is at a severe disadvantage in timely responding to the request because there may be a lengthy lapse in time before the correspondence is referred to the appropriate department. Sending correspondence to the wrong address also increases the chances that a request for claims information may get lost.

  While we understand from CMS that this problem has been improved under the CERT program, we have heard from physicians that they continue to encounter the problem. We also understand that some Medicare carriers are highlighting a recently-revised Medlearn Matters article that emphasizes the importance of

providers responding promptly when they receive a CERT request for medical documentation. Some physicians report that responses to such requests are delayed when the request does not go directly to the medical records department or if the CERT contractor is unfamiliar to the physician. **Thus, we recommend that PPAC urge CMS to ensure that the RACs send correspondence to the appropriate address. We also urge PPAC to recommend that CMS and the RACs significantly educate physicians and other providers as to the identity of the RACs and how to fulfill their requests.**

- **Monitor incentives for the RACs to identify underpayments and ensure that underpayments are referred to the appropriate contractor for payment.** CMS has established that pursuant to the MMA the RACs will identify underpayments and overpayments and recover overpayments. Further, since the RACs will not be paid for finding underpayments, it is unclear whether the RACs will have an incentive to identify underpayments. CMS believes that there are incentives for the RACs to identify underpayments. CMS noted, for example, the RACs' intent to foster a constructive relationship with physicians and providers. CMS has assured the physician and provider community that once a RAC finds an underpayment, it will be referred to the appropriate contractor for processing and appropriate payment.

- **Clarify that the RACs' scope of review activities on Part A claims will be limited to the Part A provider.** Physicians are concerned that a RAC review of the physician medical record (created while treating a patient whose care was reimbursed under Part A) may be triggered in the process of reviewing Part A claims. Thus, the RACs should clarify to CMS that review of Part A claims will be limited to the Part A provider and not extended to the physician medical record.

The AMA is committed to working with CMS and the RACs to ensure the most effective communication with the physician community throughout the RAC demo process, as well as a constructive, educational focus should the demo shift its focus to Part B claims.

PART D PRESCRIPTION DRUG PROGRAM

The new Part D prescription drug benefit, established under the MMA, will become effective January 1, 2006, and Medicare beneficiaries will need to begin enrolling in the program in the fall of this year. As this enrollment process is undertaken, beneficiaries will need significant guidance in determining such factors as how the process works, which plan is best for them and coverage and benefit levels. A 2004 Kaiser study found that 38% of Medicare beneficiaries surveyed said that they would turn to their physicians for help in deciding whether to enroll in the new drug benefit. A new Kaiser survey conducted March 31-April 3, 2005, found that 49% of seniors would turn to their physicians for help. Only 23% indicated they would turn to the Medicare program itself.

The AMA urges PPAC to strongly recommend that CMS ensure that a broad-based education program concerning enrollment in the Part D drug benefit is in place for Medicare beneficiaries. Physicians must be able, when asked, to refer beneficiaries to a user-friendly, easily identifiable and accessible source within the Medicare program for guidance on these important matters. Significant amounts of time spent on advising patients about their choices under Part D and their new Medicare Advantage plan options will only take away from the already limited amount of time that physicians have to spend on patient care. CMS must find a way to make it simple and easy, even for patients without internet access, to determine what is and is not covered by drug plan formularies and what their cost-sharing obligations are likely to be under various plans. It is critical that CMS establish a reliable plan for educating beneficiaries that will make then feel confident that they have all the information they need to make good choices for their health.

Further, physicians cannot absorb another unfunded mandate in acting as the primary source of information about the new drug benefit, especially on top of expected Medicare payment cuts of 26% over six consecutive years, beginning January 1, 2006, as well as ongoing paperwork burdens, and skyrocketing medical liability premium costs. Physicians are the cornerstone of the Medicare program. If physicians can no longer afford to treat Medicare patients, ironically, it would be difficult for beneficiaries to have access to the new prescription drug benefit.

We are also concerned about the impact of the Part D drug benefit program on utilization of Part B physicians' services. As we have previously discussed with PPAC, while the new Part D drug benefit is clearly good for patients, this benefit will significantly expand expenditures for physician services because beneficiaries who previously could not afford to purchase drugs will visit physicians to get prescriptions. Moreover, these patients will have to be monitored by the physician for the impact of the drugs, with office visits and laboratory tests, and may need to be seen for other conditions discovered at the time of the visit.

Increases in the utilization of physician services, if not adequately reflected in the sustainable growth rate (SGR) target, will cause actual Medicare physician spending to exceed the SGR target, triggering additional cuts in payments to physicians. **We recommend that PPAC urge CMS to ensure that the impact of the drug benefit is adequately reflected in the SGR.**

Finally, we want to note that education about the new Medicare Advantage choices and the Medicare Advantage prescription drug plans is also very important. Beneficiary decision making for 2006 will be complex. It is possible that, faced with the choice of managing three different health plans – their underlying Part B coverage, Medicare supplemental coverage, and drug coverage – more beneficiaries will explore the possibility of enrolling in Medicare Advantage. **We recommend that PPAC urge CMS to require Medicare Advantage plans to provide beneficiaries with clear and standardized information on what is and is not covered by the plan, as well as on their cost-sharing obligations.**

COMPETITIVE ACQUISITION FOR DRUGS

Overview of the CAP

The AMA appreciates CMS' efforts in developing a proposal to implement a new and complex competitive bidding program for Part B drugs. This program, which would become an alternative to payments based on the average sales price plus six percent, is untested and there is uncertainty about what the final program will look like. Therefore, the AMA recommends that CMS issue an interim final rule with comment rather than a final rule so that the physician community and other stakeholders can submit additional comments on the CAP. As noted later in this document, we also believe that, at a minimum, CMS should require vendors to offer all the drugs that physicians have been unable to purchase at 106% of the Average Sales Price (ASP). We would like to see additional discussion regarding the legal liability of the vendors in cases where drugs have been damaged or tampered with in the delivery process. **In addition, we urge PPAC to recommend that CMS include a plan for protecting beneficiaries who cannot reimburse the vendor for the patient copays associated with these drugs.**

The AMA is very concerned that the combined impact of cuts in drug payment rates and scheduled across-the-board cuts related to the Sustainable Growth Rate (SGR) will force many physicians to stop providing these drugs in their offices. In that event, patients will be forced to seek this care from hospitals, where they are likely to face higher costs than they do currently. **With that in mind, we urge the Administration to take an active role in averting projected cuts of 26% in the physician conversion factor over the next six years, including removal of physician-administered drugs from the SGR, retroactive to the SGR base year.**

Further, CMS should not include CAP prices in determining ASPs. To do so would set up a perpetual downward spiral as CAP prices lead to reductions in ASPs, which then lead to additional reductions in the next year's CAP prices, and so on. Physicians already find it impossible to purchase some drugs at the ASP. Further reductions created by the inclusion of yet another discounted purchaser will only exacerbate the current problems, eventually forcing all physicians into the CAP and greatly diminishing their ability to determine which drugs are provided to their patients and to control the quality of those drugs.

Categories of Drugs to be Included under the CAP

Section 303(b) of the MMA establishes a competitive acquisition program (CAP) for the acquisition and payment for Part B covered drugs and biologicals furnished on or after January 1, 2006. Beginning January 1, 2006, physicians will have a choice between acquiring and billing for Part B covered drugs under the Average Sales Price (ASP) drug payment methodology or electing to receive these drugs from vendors selected for CAP under a competitive bidding process. The key purposes of the CAP are to provide an alternative method for physicians to obtain Part B drugs to administer to their Medicare

patients and to reduce drug acquisition and billing burdens for physicians. In implementing the CAP, CMS is required to establish categories of competitively biddable drugs and biologicals and to phase in the program with respect to those categories, as it deems appropriate.

With respect to the scope of the CAP, CMS is proposing to limit the CAP, at least initially, to drugs administered in physician offices – e.g., those drugs that are administered as "incident to" a physician's service – even though the statute provides a broader definition of "competitively biddable drugs and biologicals" to include drugs administered through durable medical equipment (DME) (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). **The AMA agrees with this approach. CMS can always re-examine the scope of the program after the CAP is implemented and there is enough data to study how the program is working.**

CMS seeks comments on the different options it is considering for phasing in the CAP. In terms of the drugs covered by the program, one option would be to include all drugs furnished incident to a physician's service; a second option would be start with a limited set of drugs typically used by oncologists; and a third option would be to begin with a smaller number of drugs used by other specialties.

Previously, the AMA took the position that because a competitive bidding system for physician administered drugs is new and untested, CMS initially should allow competitive bidding for only a few drugs. However, we can see both sides of the phase-in issue. For example, beginning with specialties that use fewer Part B-covered drugs would limit the scope of the initial program and provide an opportunity for the agency and stakeholders to identify issues and problems before phasing in larger drug classes such as those used by oncologists. Likewise, beginning with drugs used by a single specialty, i.e., oncology, would allow CMS to deal with a more limited and homogeneous set of implementation issues before expanding the CAP. On the other hand, as CMS points out in the preamble of the proposed rule, beginning with a limited program might be too narrow in scope to really be useful in identifying issues and problems. Another disadvantage is that restricting the list of drugs or specialties could also limit the number of bidders.

Most important, limiting the scope of the program initially would not fulfill Congressional intent of providing physicians with an alternative to ASP for acquiring Part B drugs beginning on January 1, 2006. **Therefore, we urge PPAC to recommend that CMS make the CAP available to all physicians for all drugs that are furnished incident to a physician's service beginning in 2006. If, however, CMS decides to phase in the CAP, then at the very least, CMS should include all of the "problem" drugs – e.g., the Part B drugs that physicians have reported are unavailable at ASP.**

There have been widespread reports of difficulties with some drugs, including several of the drugs used for treating bladder cancer as well as Levaquin, rocephin, and saline solution. Even when the difference between the ASP and the physician's purchase price

appears to be rather modest, losses can mount up quickly if the drug is used in large quantities. It is our understanding that CMS's Physicians Regulatory Issues Team (PRIT) has identified at least 40 "problem" drugs. If the intent of the CAP truly is to provide a safety net, these drugs should all be included in the initial CAP offerings.

The AMA urges PPAC to recommend that if CMS chooses to phase in CAP one category of drugs at a time, the opportunity to acquire drugs through the CAP should be available to any specialty that requires the drug for any purpose, including off-label use. For example, the rule suggests that CMS might begin by covering the most prevalent drugs administered by oncologists, including infliximab (Remicaide). The rule does not specify whether other specialties (rheumatologists and gastroenterologists) who use this drug to treat other diseases (rheumatoid arthritis and Crohn's Disease) would also be permitted to participate in the CAP under this option. We see no reason to limit the CAP alternative only to oncologists in this instance and believe the rule needs clarification on this point.

Competitive Acquisition Areas

CMS seeks comment on possible approaches for defining the competitive acquisition areas (CAA) required by statute for the CAP. The basic options are creating a national CAA, regional CAAs, or statewide CAAs; each approach has pros and cons. **While we do not have a particular preference about the competitive acquisition areas, we urge PPAC to recommend that CMS fully implement the CAP nationwide, e.g., in all acquisition areas, from the start of the program.**

Operational Aspects of the CAP

Statutory Requirements Concerning Claims Processing

The statute provides that a vendor may not provide drugs to a physician participating in the CAP unless the physician submits a prescription for each patient to the vendor. For purposes of the CAP, CMS is proposing to interpret "prescription" to include a written order submitted to the vendor. The proposed rule does not specify what format(s) may be used, although in the preamble, CMS indicates that the order may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order**. We urge PPAC to recommend that CMS ensure the process for ordering drugs be as user-friendly as possible, and structured to be as similar as possible to the way a physician currently orders drugs. The process for ordering drugs should include phone, fax, and the internet. CMS should specify in the final rule that these formats may be used.**

Claims Processing Overview

1. Vendor's obligation to fill order

CMS sets forth in detail proposed requirements for both physicians and vendors participating in the CAP. However, although physicians are required to submit a written order to their CAP vendor in order to acquire drugs, there is no requirement that a vendor must fill every valid (e.g., properly completed) order received from a physician. **While this might be implicit, we urge PPAC to recommend that CMS make this obligation on the vendor's part explicit in the final rule.**

2. Information Required with Order

CMS seeks comments on the information required to be part of the drug order. While information about the patient's secondary insurance, if any, is appropriate, much of the other information, such as "frequency/instructions," anticipated date of administration, and "additional patient information, such as date of birth, allergies, Ht/Wt/ICD-9, etc," is either unnecessary or inappropriate.

We urge PPAC to recommend that information about "anticipated date of administration" should be changed to allow a range of dates on which administration is anticipated for a particular patient. It is not always possible to predict the exact date on which drugs will be administered. A patient's schedule for therapy often changes based on the patient's condition, or because a patient cancels or reschedules an appointment. It is duplicative to ask for information about "Frequency." The vendor does not need such information to fill the order and can obtain this information from the claim form filed by the physician. Finally, we do not understand why the physician should be required to provide "additional patient information."

3. Filing of Physician Drug Administration Claim and Vendor Payment

Under the statute, Medicare payment to the vendor, and any applicable deductible and coinsurance, is conditioned upon actual administration of the drug to the patient for which it was ordered. However, CMS is going beyond this statutory requirement by proposing that payment to the vendor also would be dependent upon the filing of the drug administration claim by the physician and approval of the physician's claim by the CMS claims processing system. Moreover, the physician would be required to submit all claims for drug administration services within fourteen days of the date of service. Filing within such a tight time frame would be impractical and difficult for many practices. **We recommend that PPAC urge CMS to allow physicians at least 30 business days after the date of drug administration to submit claims.**

We also question why payment to the vendor should have to wait not only until the physician has filed the drug administration claim, but also until the claim has been approved. CMS indicates in the preamble that it is considering, but not proposing at this time, making partial payments to vendors. **The AMA favors making partial payments**

available to vendors. This would encourage greater participation in the CAP by both vendors and physicians by preventing cash flow problems for vendors and eliminating potential disputes between physicians and vendors over how rapidly the physician must file their claims. However, physicians should not be involved in any reconciliation that might arise between the vendor and the CMS claims processing carrier.

4. Timely deliveries and emergencies

The AMA supports CMS' proposal that in emergency situations, drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians as long as all of the following conditions are met: 1) The drugs were required immediately; 2) The physician could not have anticipated the need for the drugs; 3) The vendor could not have delivered the drugs in a timely manner; and 4) The drugs were administered in an emergency situation. With respect to how to define timely delivery for emergency drug shipments, CMS proposes that emergency drug orders would be furnished on the next day for orders received by the vendor before 3 p.m., but seeks comment on the feasibility of providing same-day deliveries for emergency orders (preamble at page 10760).

We urge PPAC to recommend that CMS lay out more detailed criteria on what the agency would regard as an emergency to prevent misunderstanding and possible audits and repayment demands in the future. It seems clear that many patients with infectious diseases often would need immediate treatment and even next day or 24-hour delivery would not be prompt enough in these situations. However, there are many other situations where delayed administration is not life-threatening but still would impose a substantial hardship or lead to unreasonable delays in the delivery of effective therapies. For example, some patients may travel three to four hours for their treatment. Others may need immediate care to relieve intense pain or prevent a particularly aggressive cancer from spreading further. Is this an emergency or will these patients be told to come back another day if the drug they need is not available because it is this patient's first visit? What if the vendor ***could*** have delivered the drug but ***didn't*** due to some glitch in the administrative process?

One possibility CMS should consider is the creation of a group of physicians and patients to help flesh out the definition of an emergency. In the meantime, the AMA believes that emergency orders should be filled on a same-day basis when possible. If that is not possible, physicians should be allowed to buy the needed drug from a source other than the CAP vendor or take it from existing stock. They should then have two options: (1) order the drug from the vendor to replace their private stock or (2) bill for the replacement drug using the ASP methodology.

The latter option could be modeled after the existing "furnish as written" provision, which allows physicians to "obtain a drug under the ASP methodology" in certain situations. This would reduce administrative hassles associated with replenishing the physician's supply and potentially avoid unnecessary hospital stays for patients that could have been treated more cost effectively in physicians' offices. In addition, care must be

taken to ensure that whatever mechanism is implemented is of minimal burden to both the physician and patient.

5. Disposition of Unused Drug

The proposed rule provides that if a drug is not administered on its "anticipated" date, the physician should notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law." While the preamble explains the process to be followed if agreement is reached that the drug could be maintained in the physician's inventory, there is no guidance, in the preamble or the rule, about what happens if this is not the resolution. If the vendor requires the physician to return the unused drug, is the physician required to comply? If the physician sends the drug back, is the physician allowed to charge the vendor for shipping fees? Could the vendor require the physician to mitigate the vendor's loss by offering to administer the drug to another Medicare patient? **We recommend that PPAC urge CMS to address these questions in the final rule.**

6. Vendors and Drug Categories

We agree with CMS that physicians who elect to participate in the CAP would continue to bill their local carrier for drug administration. **We also support allowing physicians to choose the categories of drugs they wish to obtain from vendors, and we urge PPAC to recommend that CMS include this in the final rule.** Finally, we agree that for those drugs that are not included in the CAP and for drug categories that the physician does not select, the physician would continue to bill and be paid under the ASP methodology.

7. Payment for Administrative Costs

We disagree with CMS's decision not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program. On page 10755 of the Preamble, CMS states "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." We question how CMS came to such a conclusion. Although participating in the CAP means that physicians will not have to purchase drugs and bill Medicare patients for co-payments, there are many administrative requirements in CAP that will necessitate just as many, if not more, clerical and inventory resources for physician practices.

Ordering drugs under the CAP could cost significantly more than under the reimbursement system. Under the reimbursement system, physicians generally maintain an inventory for each type of drug and order additional units when the inventory falls below a certain level. For example, oncologists often use an automated storage and inventory control system that tracks the remaining amount of each drug. By contrast to this relatively simple method of ordering in bulk, the CAP requires orders to be submitted

to the vendor for each patient, and those orders would need to provide significant patient-specific information instead of simply the number of units requested.

The proposal would also require a different type of inventory system than practices currently use. An inventory record would have to be created for each drug. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. We have been advised by some of the medical specialty organizations that physicians currently do not maintain similar inventory records, and the additional work involved would appear to be substantial.

Storage costs would be at least as large under the CAP as under the reimbursement method, and storage may be more difficult to manage. Although the proposal states that the CAP drug inventory would not need to be segregated from other inventory, there may need to be some form of segregation so that the office staff can ascertain the amount of inventory available for non-Medicare patients. For example, if a physician has ten vials of a particular drug on hand, it will not be clear from visual observation whether all of the vials have been received from the vendor for Medicare patients or whether part of the inventory is available for non-Medicare patients.

At the billing stage, there would be more work under the CAP than under the reimbursement method. The content of the claims would be identical in most respects under both systems, but the CAP claim would need to include a prescription number for each of the drug codes billed. Retrieving the prescription number for each drug and including it in the claim would be significant additional work beyond what is now required. For physician practices not currently using prescription numbers, additional non-reimbursable costs will be incurred to make the necessary software changes to submit these data elements to Medicare.

CMS states in the preamble that it is not their intention to restrict the physician's flexibility when ordering a drug from a CAP vendor or to require that a physician would order drugs differently from a CAP vendor than the way a physician would order from a non-CAP vendor. We understand that in developing this proposal, CMS is constrained by statutory requirements and the existing Medicare claims processing rules. However, CMS's proposal would require physicians to order drugs differently under the CAP program.

We recommend that PPAC urge CMS to simplify claims processing under the proposal as much as possible to alleviate the administrative burden on physicians, and to develop a mechanism to reimburse physicians for any additional administrative costs they incur for participating in the CAP. Such payments should not be included in the SGR or if they are, should be adjusted for in the law and regulation component of the formula.

Dispute Resolution

Under the proposal, only the physician would have appeal rights in the case of claims that are denied for medical necessity or other reasons. If the vendor dispenses drugs and cannot obtain Medicare payment because the physician's claims are denied, CMS is proposing that the vendor should have the right to complain to its carrier if the losses with respect to an individual physician exceed an "acceptable threshold." If that occurs, the carrier will counsel the physician to submit clean claims and to pursue administrative appeal rights on denied claims. If problems persist, the carrier could recommend to CMS that the physician be suspended from the CAP, and CMS would decide whether to do so. CAP vendors would also be required to have procedures to handle complaints about service from physicians and about billing issues from patients.

We urge PPAC to recommend that CMS clarify the extent of the physician's responsibility to appeal denied claims. The physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations). Further appeals should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.

The proposal indicates that beneficiary billing disputes would be handled by the beneficiary first using the vendor's grievance process and, if the beneficiary is dissatisfied with the result, requesting intervention by the vendor's carrier. The carrier would investigate the facts and then facilitate correction to the claim record and beneficiary file.

This process should be made very clear to beneficiaries. CMS should develop standard language that vendors would be required to include in every bill to beneficiaries explaining the grievance process and the method for subsequently appealing any issues to the designated carrier. The information should make clear that the beneficiary's physician is not involved in the billing and has no authority to resolve any disputes.

The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing. The preamble states only that the Medicare carrier will attempt to resolve such disputes if the vendor and the physician or beneficiary cannot. **We believe that the process should be more definitive.** At a minimum, the carrier should be given a clear mandate to resolve disputes, the process for doing so should be clear and should offer the parties an opportunity to participate in a meaningful way.

Contracting Process – Quality and Product Integrity Aspects

The proposed regulation includes a number of provisions intended to ensure that the vendors provide drugs that meet quality and product integrity standards. **We urge PPAC to recommend that CMS address the following concerns:**

1. Vendors should be prohibited from opening drug containers

CMS is authorized by the statute to impose product integrity safeguards. The final rule should deal with the authority of vendors to open drug containers. For example, if a vendor believes that a particular patient's order does not require a full container of drug, the vendor may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity would be unacceptable. Vendors should be clearly required to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

2. Return of damaged or suspicious drugs

Physicians should be permitted to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The physician should not be required to seek a remedy from the company that delivered the product.

3. Vendors should be required to carry substantial liability insurance

There should be a requirement that vendors carry substantial liability insurance. If vendor errors cause harm to patients, their liability for damages could be substantial. The final rule should require liability insurance in sufficient amount to cover potentially serious adverse events.

4. Vendors should be required to indemnify physicians for any losses they cause

If actions by the vendors in handling the drugs result in injury to patients, it is possible that claims will be made against the physicians who administered the drugs. The final rule should require vendors to indemnify physicians for any losses, damages, and costs (including attorneys fees) incurred by the physician as a result of the vendor's negligence, errors, or omissions.

5. CMS should audit compliance with and enforce the standards

CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

Bidding Entity Qualifications

Under the proposed rule, vendors would be considered covered entities under HIPAA. The AMA believes CMS should clarify whether vendors have the right to sell physician-specific data. If the vendors do have this right, the vendors should be required to disclose

their policies on any non-CAP data transfers that they might make so that physicians may take those policies into account before selecting a vendor or signing a CAP election agreement. **Similarly, we urge PPAC to recommend that CMS clarify the extent to which vendors may market to patients.**

CAP Bidding Process-Evaluation and Selection

CMS proposes to make adjustments to the vendors' payment schedule on an annual basis. There would be more frequent adjustments in certain cases, such as when a new drug is introduced, but such adjustments would be done only quarterly. The proposal is silent as to when vendors would be obligated to provide newly approved drugs to physicians. CMS should revise the vendor payment schedule as new drugs are approved and require vendors to make such drugs immediately available to physicians. **If it is impossible for vendors to do so, physicians should be able to obtain new drugs outside the CAP. Vendors also should be prohibited from making deletions or substitutions in the formulary mid-year, and we urge PPAC to make this recommendation to CMS.**

Physician Election Process

Under the proposal, physicians would annually decide whether to participate in the CAP. If a physician's selected CAP vendor is terminated from the program or leaves the program mid-year, we recommend that physicians should have the option of ending participation in the CAP or choosing another vendor. The proposed rule is silent regarding a physician's right to leave the program or select another vendor mid-year if dissatisfied with a vendor's service. **We urge PPAC to recommend that the final rule allow a physician to change vendors or leave the program if there is a service problem with a vendor.**

Impact on Patients

Finally, the AMA would like to express its concerns regarding CAP's potential impact on Medicare patients. Co-payments for most of the drugs that will be involved in the CAP are significant. For patients who lack any supplemental coverage, the costs are often prohibitive. Today, physicians waive the co-payments for a significant number of these patients. However, it seems unlikely that vendors will be willing to absorb this loss. In fact, even those patients who do have supplemental insurance could face substantial difficulties due to possible differences between the drugs covered under these policies and those provided by the vendor. **Although the proposed rule does not address this issue, we urge PPAC to recommend that the final rule lay out a process for dealing with these situations and CMS should monitor the situation closely.**

We appreciate the opportunity to provide our views on the foregoing and look forward to continuing to work with PPAC and CMS in resolving these important matters.